

REMARKS

Claims 37, 89-93, and 107-131 are pending in this case. Claim 132 is added herewith. Thus, with the entry of this amendment, claims 37, 89-93 and 107-132 will be active in this application.

I. The Interview

Applicants thank Examiner Bui and Supervisory Examiner Housel for the interview on July 27, 2004 with Dr. Jeffrey Schlom, who is a co-inventor on the above application, and the undersigned representative of applicants. During the interview, the following matters were discussed:

(1) The enablement of claim 93 and the need to separate the "pre-malignant cells and tumor cells" from claim 93 into a new claim, so as to provoke a restriction requirement between the new claim and claim amended claim 93.

(2) The written description support in the specification for the antigens listed in claims 107 to 120.

(3) The proposed amendment to claim 37 that would overcome the double patenting rejection and the rejection for obviousness.

(4) The proposed Rule 132 declaration in support of the novelty and non-obviousness of the invention.

II. Rejections under 35 USC § 112

The PTO has rejected claim 93 for the alleged reason that the specification fails to present data related to each "virus, bacteria and protozoan infection as well as a pre-malignant cell and tumor cell development." Page 2, last paragraph. In response, applicants herewith amend claim 93 to remove "pre-malignant cell and tumor cell development." This embodiment now appears in new claim 132. This amendment is made pursuant to Supervisory Examiner Housel's suggestion at the interview. Applicants expect to receive a restriction requirement between amended claim 93 and

new claim 132. The purpose of this amendment is to advance the allowance of amended claim 93 and to pursue the subject matter of new claim 132 in a different application in a different art unit.

The Examiner also rejected claims 89-93, 107-120 and 122-125 under 35 USC § 112, first paragraph, for lack of a written description, for the asserted reason that the specification fails to describe all the antigens listed in claims 107-120 and 122-125. It is applicant's understanding that this rejection will be withdrawn in view of the present amendment and applicants explanation of unexpected results.

III. Double Patenting

In the present Office Action, the PTO maintained the rejection of claims 37, 107-108, 120, 122 and 123 as allegedly obvious over claims 1-6 of U.S. Patent No. 6,548,068. In response to this objection, applicants herewith amend claim 37 to clarify that the host cell comprises nucleic acid sequences encoding a combination of B7, ICAM-1 and LFA-3. This specific combination is not suggested in claims 1-6 of the '068 patent. Additionally, even if such a specific combination were suggested-- which it was not-- the results obtained using B7, ICAM-1 and LFA-3 have been dramatic. The specification describes in Example 27 a-d that B7, ICAM-1 and LFA-3 ("TRICOM") cooperate synergistically in enhancing T-cell proliferation. In the attached Rule 132 Declaration, Dr. Schlom describes the unexpected results. Specifically, in paragraphs 6 and 7, Dr. Schlom points out that the sum of activity of each molecule is far exceeded by the combination. Additionally, even the combination of B7-1 and ICAM-1 is much inferior to TRICOM.

It also cannot be assumed that multiple costimulatory molecules work in an additive fashion. In fact, there is reason to believe that some combinations of molecules might compete or somehow interfere with each other. In paragraph 8, Dr. Schlom describes work in his laboratory that used the same assay described in Example 27 but which added a fourth costimulatory molecule, CD70. Although one might expect the fourth molecule to further enhance T-cell proliferation. This is not what happened. Rather, the addition of this particular fourth molecule had an inhibitory

effect, relative the results obtained with TRICOM, alone. These results are set forth in the attachments to Dr. Schlom's declaration.

In view of the Rule 132 Declaration of Dr. Schlom and the data presented in the specification and Dr. Schlom's attachments, applicants respectfully request the PTO to reconsider and withdraw the double-patenting rejection.

III. Rejection under 35 USC § 102

The PTO has rejected claims 37, 107-108, 120, 122 and 123 under 35 USC § 102(e) over the '068 patent. In response, applicants point out that the '068 patent does not teach the specific combination of B7, ICAM-1 and LFA-3, as recited in amended claims 37 and 89. In order to arrive at the claimed invention, one would need to pick and choose from a larger number of co-stimulatory molecules. Nothing would direct one to this specific combination. In view of this amendment, applicants respectfully request the Examiner to withdraw this rejection.

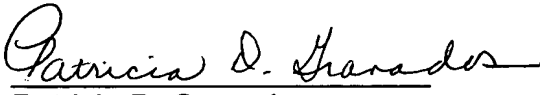
IV. Rejoinder

Applicants respectfully request that upon an indication of allowance of the present claims that the previous non-elected claims be rejoined with this application. A Restriction Requirement issued January 27, 2003 (Paper No. 16) to which applicants responded by electing claims 37 and 89 to 93.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 912-2142 should there be any questions.

Respectfully submitted,


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